UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA ex rel. LAURIE SIMPSON,

Honorable John Michael Vazquez United States District Court Judge

Plaintiff,

v.

BAYER CORPORATION, et al.,

Civil No. 05-3895(JLL)(JAD)

Defendants.

DEFENDANTS' RESPONSE TO THE UNITED STATES APPEAL OF THE SPECIAL MASTER'S AUGUST 24, 2020 ORDER AND OPINION DENYING RELIEF PURSUANT TO FED. R. CIV. P. 45(d)(1) AND 45(d)(2)(B)(ii)

Table of Contents

BAC	KGRC	OUND	2	
	A.	The District Court's Partial Summary Judgment Decision	2	
	B.	Bayer's Subpoenas Aimed At Understanding CMS's Payment Decisions And Processes	3	
	C.	Bayer's Extensive Negotiations And Efforts To Reduce Any Possible Burden On The Government	4	
	D.	The Motion To Quash And The Government's Belated Request For Sanctions And Cost Shifting	8	
	E.	The Special Master's Discretionary Decision Denying Sanctions And Cost Shifting.	9	
ARG	UMEN	NT	.10	
I.	Stanc	dard Of Review10		
II.	The Special Master Properly Exercised His Discretion By Denying The Government's Belated Request For Sanctions and Cost Shifting			
	A.	The Special Master Properly Determined That This Case Did Not Present "The Most Egregious Of Circumstances" To Warrant Sanctions Under Rule 45(d)(1).	.11	
		1. The Special Master correctly found that this case did not present egregious circumstances	.12	
		2. The Special Master correctly determined that the Government failed to establish an undue burden, or even a cognizable burden.	.17	
	B.	Cost-Shifting Under Rule 45(d)(2)(B) Is Inapplicable Absent A Court Order Compelling Compliance With A Subpoena	.18	
CON	ICLUS	ION	.21	

TABLE OF AUTHORITIES

Page(s) Cases In re Am. Kidney Fund, Inc., No. TDC-17-1787, 2019 WL 1894248 (D. Md. Apr. 29, 2019)12, 17, 19, 20 Builders Ass'n of Greater Chi. v. City of Chicago, No. 96 C 1122, 2002 WL 1008455 (N.D. III. May 13, 2002)......14 Fuller v. Insys Therapeutics, Inc., No. 2:17-cv-07877, 2018 WL 4941789 (D.N.J. Oct. 11, 2018)........11 Goldberg v. Amgen, Inc., Gunter v. Ridgewood Energy Corp., Havens v. Maritime Commc'ns/Land Mobile, LLC, Lee v. Va. State Bd. of Elections, Legal Voice v. Stormans Inc., Linder v. Calero-Portocarrero, Mallinckrodt LLC v. Actavis Labs. FL, Inc., No. 2:15-cv-3800, 2017 WL 5476801 (D.N.J. Feb. 10, 2017)20 Mattel, Inc. v. Walking Mountain Prods., 353 F.3d 792 (9th Cir. 2003)14 McCabe v. Ernst & Young, LLP, In re Modern Plastics Corp.,

Molefi v. Oppenheimer 1r., No. 03 CV 5631(FB)(VVP), 2007 WL 538547 (E.D.N.Y. Feb. 15, 2007)
Mount Hope Church v. Bash Back!, 705 F.3d 418 (9th Cir. 2012)12
P. Schoenfeld Asset Mgmt. LLC v. Cendant Corp., 161 F. Supp. 2d 349 (D.N.J. 2001)11
Ex parte Petition of Turkey, No. 2:19-CV-20107-ES-SCM, 2020 WL 2539232 (D.N.J. May 18, 2020)
R.J. Reynolds Tobacco v. Philip Morris, Inc., 29 F. App'x 880 (3d Cir. 2002)19
Rhett v. New Jersey, No. 07-1310(DRD), 2007 WL 1456199 (D.N.J. May 14, 2007)10
Saint-Jean v. Emigrant Mortg. Co., No. 11-CV-2122 (SJ), 2015 WL 13735434 (E.D.N.Y. Oct. 7, 2015)
SAJ Distribs., Inc. v. Sandoz, Inc., No. 08-1866(JAP), 2008 WL 2668953 (D.N.J. June 27, 2008)
Swasey v. W. Valley City, No. 2:13-cv-00768, 2016 WL 6090843 (D. Utah Oct. 18, 2016)19
<i>Tiberi v. CIGNA Ins. Co.</i> , 40 F.3d 110 (5th Cir.1994)
Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989 (2016)
W. Convenience Stores, Inc. v. Suncor Energy (U.S.A.) Inc., No. 11-cv-01611-MSK-CBS, 2014 WL 1257762 (D. Colo. Mar. 27, 2014)
Statutes
False Claims Act

Other Authorities

45 C.F.R. § 2.3	15
Fed. R. Civ. P. 45	passim
Fed. R. Civ. P. 53(f)	10
Fed. R. Civ. P. 72(a)	10
Local Civ. R. 72.1	10

The Special Master's discretionary decision to deny sanctions was correct, and the Government has failed to show that the decision was clearly erroneous, contrary to law, or an abuse of discretion. As the Special Master found, there were no "egregious . . . circumstances" meriting sanctions under Federal Rule of Civil Procedure 45(d)(1). *SAJ Distribs., Inc. v. Sandoz, Inc.*, No. 08-1866(JAP), 2008 WL 2668953, at *3 (D.N.J. June 27, 2008). Bayer engaged in normal advocacy, fully participated in good faith in numerous meet-and-confers, and repeatedly engaged the Government to discuss alternatives that would have reduced or even eliminated the Government's purported burden. Further, the Government's inability *to spend* millions of taxpayer dollars to destroy boxes, which had been stored for decades, is not a cognizable burden, and the Government cited no authority in support of its novel and overreaching position.

The Government's argument under Rule 45(d)(2)(B) is equally meritless. Cost shifting is permitted only when there is a court "order compelling production and inspection" with a previously issued subpoena, and here, there was no such order. Nor was there compliance with any such subpoena, as would be required for the Government to prevail, because the Government refused to produce the documents at issue and the Special Master granted the motion to quash.

These issues "are committed to the discretion" of the Special Master, W. Convenience Stores, Inc. v. Suncor Energy (U.S.A.) Inc., No. 11-cv-01611-MSK-

CBS, 2014 WL 1257762, at *23 (D. Colo. Mar. 27, 2014). Because the Special Master did not abuse that discretion, the Court should affirm the decision.

BACKGROUND

A. The District Court's Partial Summary Judgment Decision.

Relator Laurie Simpson filed this action in August 2005. In the operative complaint—the Tenth Amended Complaint—the only claims that remain are allegations that Bayer violated the False Claims Act ("FCA") by failing to comply with the Anti-Kickback Statute ("AKS") and engaging in off-label promotion.

In October 2018, Bayer and Relator filed cross-motions for partial summary judgment. Bayer, in its motion, argued that the Government's fixed-fee payment system precluded Relator from proving the materiality of any putative statements by Bayer. The Court rejected this argument and denied both parties' motions, but proceeded to outline "what the materiality standard does require in this case." MSJ Op., ECF No. 351 at 30 (emphasis omitted). One relevant, though not dispositive, factor is "whether the Government labels an underlying statutory requirement as 'a condition of payment." *Id.*

Beyond this factor, the Court explained, "Relator must provide 'evidence that [Bayer] knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with' the AKS or the reasonable and necessary requirement as it relates to off-label drug uses." *Id.* (citing *Universal Health Servs.*,

Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989, 2003 (2016)). "Escobar instructs courts to examine the Government's practice of payment or nonpayment of claims based on the same underlying violation—claims that are noncompliant 'with the particular statutory, regulatory, or contractual requirement' at issue." Id. at 31. "Here, therefore, the Court's focus is on the Government's actual or likely conduct with respect to payment of claims that are noncompliant with the AKS or with Medicare's reasonable and necessary requirement as it relates to off-label drug uses—the two alleged underlying violations in this case." Id. at 32.1

B. Bayer's Subpoenas Aimed At Understanding CMS's Payment Decisions And Processes.

In light of the Court's holding on materiality, Bayer served subpoenas for documents on the Government, including to the Centers for Medicare and Medicaid Services ("CMS"), the agency responsible for approving or denying the claims at issue.² Through those subpoenas, Bayer specifically sought to learn whether the "Government consistently refuses to pay claims in the mine run of cases based on noncompliance with" the two legal requirements at issue. *Id.* at 30. Because "*Escobar* instructs courts to examine the Government's practice of payment or nonpayment of claims based on the same underlying violation," *id.* at 31, Bayer

¹ If Relator meets her burden, one defense for Bayer is showing that "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated." *Id.* at 32.

² Bayer also issued a subpoena after the oral argument, in which the Court expressed its views on the materiality inquiry.

requested documents pertaining to such practice. Bayer also requested certain other information not relevant to the dispute currently before the Court.

C. Bayer's Extensive Negotiations And Efforts To Reduce Any Burden On The Government.

In response to Bayer's subpoena, CMS produced only 253 documents, most of which are irrelevant; only 46 documents fall within the timeframe identified by the Special Master as relevant, and many of those are still not relevant to the issues in this case. More importantly, CMS produced no evidence regarding whether it has ever denied "payment of claims that are noncompliant with the AKS or with Medicare's reasonable and necessary requirement as it relates to off-label drug uses—the two alleged underlying violations in this case." *Id.* at 32.

To address the deficiencies in CMS's production, the parties held numerous meet-and-confers. On those calls, Bayer pointed out the gaps in CMS's productions. Bayer also asked CMS whether it was aware of any instances in which CMS denied payment on account of noncompliance with the AKS or the off-label regulations. The CMS attorneys replied that they were not aware of any, and to this day, the Government still has not identified any such instance. Nor do any of the produced documents show one.

Despite the Government's failure to complete its production, the Government sought to destroy documents that it considered to be "aged"—a curious term considering the vintage of this litigation, which itself has rendered all responsive

documents quite "aged." The alleged conduct ended in 2007, so every responsive document is at least fourteen years old. And the Government, as part of its investigation, asked Bayer for information about events dating back to 1998, which the Government now claims is outside the relevant time period. Relator, for her part, has imposed no time limitation and has not agreed to the Government's proposed time period for responsive documents or any potential restriction raised by Bayer, which had sought to focus discovery. Regardless, the Government refused to produce the "aged" boxes at issue, even though the Government conceded it had not reviewed even a sample of the boxes, the contents of which were largely "unknown." *See* Klots Memorandum, ECF No. 363-4 at 1, 7; *id.* at 3. The Government sought to destroy those boxes, despite the fact that it had been maintaining for over 20 years at its own expense before Bayer asked for them.

Bayer continuously attempted to work with the Government to alleviate its asserted burden. Nearly a year ago, in October 2019, Bayer offered to review a statistically significant sample of the boxes at Bayer's expense. Gov't Br., Ex. 16 at 3. But the Government took seven weeks to respond and then refused, prolonging this dispute and increasing its own purported storage expenses. Although the Government says that Bayer rejected its prior offer to sample the boxes in July 2019, Gov't Br. at 8-9, that is a misleading version of what occurred. In fact, the Government offered only a sampling of documents *at a single facility* in Camden,

South Carolina, *see* Gov't Br., Ex. 16 at 3-4, and never responded to Bayer's questions about how the sample would be selected. *See id.* at 4.

Months later, when the Government filed its motion to quash in February 2020, the Government represented for the first time that it was willing to provide Bayer with a significant sample of boxes from around the country, as opposed to from only one site. Gov't Br., Ex. 9 (Mot. to Quash at 4). In response, Bayer sought to meet and confer with the Government and offered to review such a meaningful sample at Bayer's own expense. Inexplicably reversing course, the Government rejected Bayer's offer.³

Bayer also made other efforts to reduce any purported burden on the Government. Through numerous letters and meet-and-confer teleconferences, Bayer worked with CMS to limit the scope of its subpoena by prioritizing requests, highlighting missing information, and narrowing the information sought. *E.g.*, Gov't Br., Ex. 14 at 3 (citing email summarizing meet-and-confer when Bayer prioritized document requests numbers 1-9 and narrowed CMS's searches to focus

³ In its briefing to the Special Master, the Government asserted for the first time that it had been willing to fly boxes from all "around the country" to Camden. Gov't Br., Ex. 15 at 3. But the Government had never made such an offer. Nor would such an offer have made any sense, considering the remoteness of Camden, South Carolina, and the fact that lead counsel for the Government and Bayer have offices in Washington, D.C., which is more than 400 miles from Camden. If the Government had been truly willing to fly in boxes from "around the country," it could have done so in a less burdensome and unusual manner.

on operational documents reflecting Medicare's processes for receiving, reviewing, paying, or denying claims).

As yet another alternative, Bayer proposed that CMS could stipulate that, to the best of its knowledge, it has never denied payment on the basis of an alleged AKS violation or off-label use. A stipulation would entirely relieve CMS of any asserted burden because Bayer would forgo any further discovery on the agency. The record to date supports the stipulation, as discovery has yet to identify a single instance of CMS ever denying payment on these grounds.

Nonetheless, the Government refused to enter into the stipulation or even to propose a viable alternative.⁴ The Government's bald assertion that the stipulation is false is belied by the evidence as well as the Government's own argument to the Special Master that it cannot verify "whether the [Government] has ever denied payment under the proffered circumstances." Opp'n to Motion to Compel, ECF No. 375 at 4. Regardless, as Bayer argued: "If the Government concludes that Bayer's proposed stipulation is incorrect, the parties can meet and confer about alternative

⁴ The Government asserts that it offered up its electronic National Claims History database, *see* Gov't Br. at 6-7, 21, but fails to mention that this database does not contain any record of CMS ever denying a claim based on an AKS violation or off-label use. Further, the electronic claims database is not a substitute for the boxes Bayer sought to review. The Government's own description of the boxes confirms they contain more than just claims data. *See* Gov't Br., Ex. 9 at 9 (noting paper claims, claim appeal files, medical records to support claims, and inquiries about claims). That is why the Government has been storing the boxes for more than two decades.

language. But the Government has refused to do so, and has disregarded emails from Bayer seeking to address the issue." *See* Gov't Br., Ex. 14 at 4.

D. The Motion To Quash And The Government's Belated Request For Sanctions And Cost Shifting.

In October 2019, the Government moved to quash Bayer's subpoena, in part, with respect to the "aged" boxes. The Government did not seek sanctions or costs in its motion or reply brief. In March 2020, the Special Master granted the motion to quash. *See* Gov't Br., Ex 11. Exercising the "significant discretion" granted under Rule 45, the Special Master concluded that "Bayer ha[d] not met its burden to demonstrate that the boxes containing the aged paper records are relevant." *Id.* at 8, 10. However, the Special Master stayed the decision so that Bayer could seek reconsideration, which Bayer did on April 9, 2020.

The Government opposed Bayer's motion for reconsideration and, in its brief, argued for the first time that it was entitled to sanctions and cost-shifting under Federal Rule of Civil Procedure 45. The Government contended that it was burdened by the inability to spend millions of taxpayer dollars on document destruction, and burdened by retaining boxes that it had possessed for more than 20 years. *See* Gov't Br. at 13 & Ex. 13 at 9. But the Government simultaneously conceded that, "to the extent the date range of the box contents [at issue] is not known, they will be retained until the date range of the box can be ascertained." Gov't Br., Ex. 13 at 4.

E. The Special Master's Discretionary Decision Denying Sanctions And Cost Shifting.

The Special Master denied Bayer's motion for reconsideration, *see* Gov't Br., Ex. 17 ("Order Denying Reconsideration"), but also denied the Government's request for sanctions and cost shifting. Gov't Br., Ex. 1 ("Order Denying Costs"). In rejecting the Government's request, the Special Master explained that "[a] plain reading of Rule 45 and courts' subsequent interpretations make clear the prerequisite of a court order compelling compliance with a subpoena for Rule 45(d)(2)(B)(ii) to apply." *Id.* at 4. Without such an order, "the Government has no basis to seek redress." *Id.*

Further, the Special Master did "not find that Bayer's subpoena to CMS was issued in bad faith or for an improper purpose," and denied relief under Rule 45(d)(1). *Id.* at 5 ("It does not automatically follow that because the Court has quashed the subpoena . . . that Bayer acted unreasonably in issuing the subpoena and that sanctions in the form of cost shifting is warranted under Rule 45(d)(1)."). The Special Master explained that Bayer engaged in "normal advocacy," and concluded that "sanctions are generally reserved for 'the most egregious of circumstances, such as when a party has clearly breached Rule 45." *Id.* at 5-6. Finally, the Special Master noted that "CMS was not required to undertake the task of collecting, analyzing, copying, or producing th[e] aged paper records," and that "the

Government has not cited any case law to support the type of cost shifting it seeks here." *Id.* at 6.

ARGUMENT

I. Standard Of Review.

"[A] magistrate judge's decision is to be overturned only when the ruling was clearly erroneous or contrary to law," and "[t]he burden of" making this "showing... rests with the party filing the appeal." *Rhett v. New Jersey*, No. 07-1310(DRD), 2007 WL 1456199, at *1 (D.N.J. May 14, 2007); *see also* Fed. R. Civ. P. 72(a); Local Civ. R. 72.1. The standard is the same for special masters. *See* Fed. R. Civ. P. 53(f). The Court should reverse only if it is "left with the definite and firm conviction that a mistake has been committed," or that the special master "misinterpreted or misapplied applicable law." *Gunter v. Ridgewood Energy Corp.*, 32 F. Supp. 2d 162, 164 (D.N.J. 1998). Discretionary decisions can be reversed only for an "abuse of discretion." *Rhett*, 2007 WL 1456199, at *2; *see also Legal Voice v. Stormans Inc.*, 738 F.3d 1178, 1184 (9th Cir. 2013).

II. The Special Master Properly Exercised His Discretion By Denying The Government's Belated Request For Sanctions and Cost Shifting.

The Special Master properly concluded that the Government failed to satisfy its burden under Rule 45. Even putting aside the fact that the Government's request

was untimely and forfeited,⁵ the Government failed to meet the requirements of either Rule 45(d)(1) or Rule 45(d)(2)(B). Indeed, in its request, the Government did not cite a single case in support of sanctions under Rule 45(d)(1), failed to establish "egregious circumstances," and identified no authority that the purported costs—mainly, saving taxpayers millions of dollars by not destroying documents—were cognizable.⁶ Moreover, as the Special Master explained, the Government disregarded the plain language of Rule 45(d)(2)(B), which "make[s] clear" that "a court order compelling compliance with a subpoena" is a "prerequisite" to trigger this provision. Order Denying Costs at 4.

A. The Special Master Properly Determined That This Case Did Not Present "The Most Egregious Of Circumstances" To Warrant Sanctions Under Rule 45(d)(1).

The Government's attempt to recover Rule 45(d)(1) sanctions is without merit. "Rule 45(d)(1) is discretionary," *Legal Voice*, 738 F.3d at 1185; *Fuller v*. *Insys Therapeutics, Inc.*, No. 2:17-cv-07877, 2018 WL 4941789, at *2 (D.N.J. Oct.

⁵ The claim was forfeited because an opposition to a reconsideration motion is too late in the day to raise new arguments and issues. *See P. Schoenfeld Asset Mgmt. LLC v. Cendant Corp.*, 161 F. Supp. 2d 349, 352 (D.N.J. 2001). Also, the Government never gave "notice of its intention to seek costs, or condition[ed] its compliance on reimbursement," until its opposition to Bayer's motion for reconsideration of the decision quashing the subpoena. *See Lee v. Va. State Bd. of Elections*, No. 3:15CV357, 2016 WL 6915308, at *3 (E.D. Va. Sept. 2, 2016). Merely objecting to the subpoena is not enough to put Bayer on notice that it would be seeking to shift the costs of storage or the loss of appropriations to Bayer. *See, e.g.*, *id.* The Special Master did not address these arguments, but Bayer preserves them here.

⁶ The Government's assertion that "[t]his loss of funds" was a particular concern in light of "the unprecedented costs and demands on agency resources from the national pandemic" is puzzling and disingenuous. Again, by not destroying the documents, CMS *spared* the taxpayers millions of dollars.

11, 2018), as "[d]eterminations of issues of 'undue burden' are committed to the discretion of the trial court," or as here, the Special Master. W. Convenience, 2014 WL 1257762, at *23. The "[u]ndue burden' is limited to harm inflicted in complying with the subpoena," In re Ex parte Petition of Turkey ("Turkey"), No. 2:19-CV-20107-ES-SCM, 2020 WL 2539232, at *6 (D.N.J. May 18, 2020), and is inapplicable "to the adjudication of related follow-on issues," *Mount Hope Church* v. Bash Back!, 705 F.3d 418, 428 (9th Cir. 2012); In re Am. Kidney Fund, Inc. ("AKF"), No. TDC-17-1787, 2019 WL 1894248, at *6 (D. Md. Apr. 29, 2019). Courts generally look to "whether the subpoena was issued in bad faith or for some improper purpose," Goldberg v. Amgen, Inc., 123 F. Supp. 3d 9, 22-23 (D.D.C. 2015), which is why sanctions "are generally awarded only in the most egregious of circumstances, such as when a party has clearly breached Rule 45." SAJ Distribs., 2008 WL 2668953, at *3; Havens v. Maritime Commc'ns/Land Mobile, LLC, No. 11-cv-993, 2014 WL 2094035, at *5 (D.N.J. May 20, 2014).

1. The Special Master correctly found that this case did not present egregious circumstances.

In its request under Rule 45(d)(1), the Government cited no authority to support its position. *See* Gov't Br., Ex. 13 (Gov't Opp. to Recon. at 8). Because Bayer's pursuit of discovery amounted to "normal advocacy," and Bayer's subpoena to CMS was not "issued in bad faith or for an improper purpose," the Special Master

properly determined that this is not one of the rare, "egregious" cases warranting sanctions. Order Denying Costs at 5-6; *accord Legal Voice*, 738 F.3d at 1185.

Indeed, Bayer's subpoena was directed at one of the core issues in this case—CMS's handling of claims and payment decisions. Bayer also made good-faith, reasonable efforts to reduce any purported burden on the Government. *Supra* p. 3-7; *W. Convenience*, 2014 WL 1257762, at *23 (collecting cases); *see also Tiberi v. CIGNA Ins. Co.*, 40 F.3d 110, 112 (5th Cir.1994) (holding that Rule 45(c) (now (d)) provides for sanctions against "one issuing a vexatiously overbroad subpoena" but reversing sanctions award where party engaged in "sufficient good faith efforts to negotiate reasonable parameters on the subpoena"). In particular, Bayer engaged in multiple meet-and-confers and exchanged a myriad of letters and communications to narrow and guide the Government's search efforts. *See supra* p. 4-7. Bayer also asked Relator if she was willing to agree to the Government's proposed temporal restriction, and she was not. *See supra* at p. 5.

In addition, Bayer offered to sample the documents at its own cost and proposed a reasonable stipulation, which would have entirely relieved the Government of any possible burden. *Goldberg*, 123 F. Supp. 3d at 23 (concluding that although "[t]he parties attempted to narrow the issues, but ultimately to no avail," sanctions were not warranted). The Government's bald assertion that Bayer has done nothing to try to relieve its purported burden is, then, not only incorrect but

also unfair. In fact, it is the Government that has repeatedly failed to negotiate with Bayer, to offer alternative proposals, or even to respond to many of Bayer's calls or emails.⁷ *See supra* p. 5-8 & n.3.

That the Government ignored and rejected Bayer's efforts to minimize its burden and costs does not refute that those efforts were made. Although the Government "was not required to... accept[]" Bayer's offers, Order Denying Reconsideration at 5, the Government's rejection of those offers and refusal to provide alternatives simply cannot provide a basis for Rule 45(d)(1) sanctions, *see* Order Denying Costs at 5 ("It does not automatically follow that... Bayer acted unreasonably"). And the fact is that the Government has been storing the documents at issue and incurring that cost for over two decades, and it could have resolved this discovery dispute if it had simply made a reasonable effort to work with Bayer instead of waiting weeks to respond and then engaging in a prolonged motion

⁷ The Government's newly cited cases (none of which were cited to the Special Master) are clearly distinguishable. All involve quintessential egregious behavior. *See, e.g., Mattel, Inc. v. Walking Mountain Prods.*, 353 F.3d 792, 813-14 (9th Cir. 2003) (affirming sanctions award by district court, which found a "clear" "pattern" of the serving party filing "*oppressive* subpoena requests" that were "served for the purpose of annoying and harassment."); *Molefi v. Oppenheimer Tr.*, No. 03 CV 5631(FB)(VVP), 2007 WL 538547, at *1, *3 (E.D.N.Y. Feb. 15, 2007) (involving a "patently frivolous and procedurally flawed subpoena," where the serving party, "aside from litigation involving the subpoena, . . . has done nothing to advance the case"); *Saint-Jean v. Emigrant Mortg. Co.*, No. 11-CV-2122 (SJ), 2015 WL 13735434, at *1, *5 (E.D.N.Y. Oct. 7, 2015) (involving "a series of deposition and document subpoenas" to *plaintiffs' counsel*, and the magistrate judge found that "the whole point of the Subpoenas was to impose a burden on plaintiffs' counsel."); *Builders Ass'n of Greater Chi. v. City of Chicago*, No. 96 C 1122, 2002 WL 1008455, at *4 (N.D. Ill. May 13, 2002) (defendant did not take "any steps to avoid imposing undue burden or expense," when it "sent out approximately *five hundred* subpoenas with identical 49-category boilerplate Riders to contractors large and small").

practice. In any event, the Government has conceded the need to retain tens of thousands of these boxes until it can assess their contents, *see supra* p. 8, confirming that Bayer's resistance to their destruction was reasonable and that these costs are therefore not compensable.

Moreover, as discussed above, Bayer's proposed stipulation is plainly supported by the record. The Government still has not shown a single instance of CMS ever denying payment on account of an alleged AKS violation or impermissible off-label use, and the Government conceded that it cannot verify "whether the Government has ever denied payment under the proffered circumstances." Opp'n to Motion to Compel, ECF No. 375 at 4. Indeed, the Government admitted that CMS has good reason to "continue to pay claims" "even when the Government has actual knowledge of the defendant's wrongful conduct." *Id.* at 19. Thus, Bayer's proposed stipulation is correct.

Regardless, the issue before the Court is not whether the stipulation is accurate, but whether sanctions should be imposed on Bayer. Significantly, Bayer has repeatedly expressed a willingness to work with the Government and to negotiate the language of the stipulation, if necessary.⁸ The Government, however, has refused to do that too, without providing any explanation.

⁸ Undoubtedly, CMS *can* make factual representations on behalf of the Department of Health & Human Services if "authorized by the Agency head." 45 C.F.R. § 2.3; *contra* Gov't Br. at 14, 24. The Government's argument that "Bayer failed to follow the HHS *Touhy* regulations," Gov't Br.

The Government's argument that the stipulation is "irrelevant" confirms that, at bottom, the Government's real concern was never with discovery but instead was with the Court's prior ruling on materiality, with which the Government disagrees. Thus, the Government now contends that an AKS or off-label violation is material as a matter of law, Gov't Br. at 5 n.3, but the Government took the contrary position before Judge Linares, MSJ H'rg Tr., ECF No. 344 at 30:3-4 (arguing that the question is a "mixed question of law and fact"), 32:2-6 (agreeing that the Government was "not taking a position" that compliance with the kickback statute "is material *per se*").

More fundamentally, the Government's position is directly contrary to Judge Linares's ruling, which was that materiality is a multi-factor inquiry, with the "focus" on "the Government's actual or likely conduct with respect to payment of claims that are noncompliant with the AKS or with Medicare's reasonable and necessary requirement as it relates to off-label drug uses." MSJ Op., ECF No. 351 at 32. And the Court made clear that "Relator must provide 'evidence that [Bayer] knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with' the AKS or the reasonable and necessary

at 23 n.8, is a make-weight because Bayer initiated the entire subpoena process via a *Touhy* request, *see id.*, Ex. 2 (CMS Subpoena), and if CMS really wants a *second Touhy* request, Bayer could easily oblige.

requirement as it relates to off-label drug uses." Id. at 30 (emphasis added). Thus, the proposed stipulation is not only relevant; it can be dispositive.

Finally, the Government makes the unfounded accusation that Bayer is using the subpoena to leverage a dismissal. Gov't Br. at 2, 9, 19, 23. This incorrect and unfair. Although the Government could certainly avoid any burden by dismissing the case—as it has done in other similar FCA lawsuits—Bayer issued the subpoena in good faith in an attempt to obtain evidence it firmly believes is relevant to Relator's claims under Judge Linares's opinion. And, as discussed, Bayer attempted to reduce the burden on the Government, which belies any suggestion that Bayer was seeking leverage. The Government's accusation is unfounded.

2. The Special Master correctly determined that the Government failed to establish an undue burden, or even a cognizable burden.

Separately, the Court should affirm the Special Master's decision because the Government "produced nothing in response" from the boxes at issue and thus endured no cognizable "burden." *See AKF*, 2019 WL 1894248, at *6; *accord Turkey*, 2020 WL 2539232, at *6. The Government has no support for the proposition that not spending money to destroy boxes is a cognizable "cost" under Rule 45. *See* Gov't Br. at 10-11 (noting funds were able to be "re-program[med]"). In front of the Special Master, "the Government [did] not cite any case law to support

the type of cost shifting it seeks here," so the Special Master declined to shift "storage fees and loss of appropriate funds" to Bayer. Order Denying Costs at 6.

The Government's unsupported assertion that its storage costs, which it allegedly incurred while *not* complying with the subpoena, amount to an "undue burden" fails as well. Once again, the Government cites no authority for its position. The Government has borne the cost of storage for decades prior to this litigation, *see* Klots Memorandum, ECF No. 363-4 at 2 (explaining the boxes had been preserved since the 1990's), and the parties likely could have resolved the issue if the Government had not ignored Bayer's efforts to do so. In any event, in response to Bayer's motion for reconsideration, the Government stated that "[t]o the extent the date range of the box contents is not known, they will be retained until the date range of the boxes can be ascertained." Gov't Br., Ex. 13 at 4. That amounts to tens of thousands of boxes that the Government continues to retain, completely undermining its position.⁹

B. Cost-Shifting Under Rule 45(d)(2)(B) Is Inapplicable Absent A Court Order Compelling Compliance With A Subpoena.

The Government's request for cost shifting under Rule 45(d)(2)(B)(2) is equally meritless. The Special Master applied a straightforward, "plain reading of

⁹ As Bayer explained in its briefing to the Special Master, the Government has frequently changed positions on whether and how many boxes would be destroyed or retained. *See* Gov't Br., Ex. 16 at 1-3 (Bayer's response to Government's surreply). These documents are subject to a pending motion to compel in front of the Special Master and a second motion to quash filed by the Government.

Rule 45" and sided with "courts' subsequent interpretations" of Rule 45(d)(2)(B). Order Denying Costs at 4. This plain reading "make[s] clear" that "a court order compelling compliance with a subpoena" is a "prerequisite" to trigger this provision. *Id*.

The Government barely musters an argument on this front, relying solely on the mistaken notion that a subpoena itself triggers this provision of Rule 45. See Gov't Br. at 28-29. But, under its plain language, Rule 45(d)(2)(B) applies only when "the serving party . . . move[s] the court for the district where compliance is required for an order compelling production or inspection," and the Court in fact enters such an "order." The mere issuance of a subpoena is, then, not enough to trigger the rule on its face. To the contrary, "[a]bsent an order, a non-party bears its own production expenses." McCabe v. Ernst & Young, LLP, 221 F.R.D. 423, 425 (D.N.J. 2004); see also AKF, 2019 WL 1894248, at *5 ("It is not enough that a court issues an order which triggers events eventually resulting in a non-party's compliance; a court must issue an order specifically 'compelling production or inspection." (emphasis added)); Swasey v. W. Valley City, No. 2:13-cv-00768, 2016 WL 6090843, at *6 (D. Utah Oct. 18, 2016). Each case cited by the Government in front of the Special Master fits this description. The Special Master did not

¹⁰ See, e.g., Legal Voice, 738 F.3d at 1181; R.J. Reynolds Tobacco v. Philip Morris, Inc., 29 F. App'x 880, 881 (3d Cir. 2002); Linder v. Calero-Portocarrero, 251 F.3d 178, 179-80 (D.C. Cir. 2001). Here, not only was there no order compelling production or inspection, but there was no

"misinterpret[] or misappl[y]" Rule 45(d)(2)(B)'s straightforward language.

Gunter, 32 F. Supp. 2d at 164.

The Government's argument fails for additional reasons as well. Before awarding costs, courts in this district have considered whether the non-party has an interest in the outcome; whether the non-party can more readily bear its cost than the requesting party; and whether the litigation is of public importance. E.g., Mallinckrodt LLC v. Actavis Labs. FL, Inc., No. 2:15-cv-3800, 2017 WL 5476801, at *4 (D.N.J. Feb. 10, 2017). Here, the Government does not even attempt to establish that these factors have been met, and for good reason. The Government's interest is unmistakable because it is the real party in interest and would receive most of any recovery the Relator might obtain. "In fact, [the Government] is the central and key non-party" to this litigation, especially since its payment of claims is central to the dispute. AKF, 2019 WL 1894248, at *8-9; W. Convenience, 2014 WL 1257762, at *23 ("Courts have held that expenses should not be shifted if the nonparty was substantially involved in the underlying transaction"). Moreover, there is no doubt that the Government is well positioned to bear the costs of storage, considering it had done so for decades prior to this litigation. See Klots

production or inspection at all, because the Government refused to comply with the subpoena. In *In re Modern Plastics Corp.*, 890 F.3d 244 (6th Cir. 2018), the subpoena recipient had actually incurred costs in "copying and producing the requested documents," and the issuer took no "reasonable steps" to mitigate those costs, *id.* at 248, 252.

Memorandum, ECF No. 363-4 at 2. And finally, of course, this case purportedly involves the public interest.¹¹

CONCLUSION

For these reasons, Bayer respectfully requests that this Court affirm the Special Master's August 24, 2020 Order and Opinion and dismiss the Government's appeal of this routine discovery decision.

Dated: September 28, 2020

Respectfully submitted, /s/ Lawrence S. Lustberg

Lawrence S. Lustberg GIBBONS P.C. One Gateway Center Newark, New Jersey 07102 Tel.: (973) 596-4731

Jonathan F. Cohn (*pro hac vice*)
Benjamin M. Mundel (*pro hac vice*)
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Tel.: (202) 736-8110

Counsel for Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare LLC

¹¹ These factors also bolster the conclusion that Rule 45(d)(1) sanctions are not appropriate. *See W. Convenience*, 2014 WL 1257762, at *23-24.